AMENDMENT OF SOLICITATION/MODIFICATION OF CONTRACT

1. CONTRACT ID CODE	PAGE OF PAGES
	1 | 7

2. AMENDMENT/MODIFICATION NO.	3. EFFECTIVE DATE	4. REQUISITION/PURCHASE REQ. NO.	5. PROJECT NO.(If applicable)
0004	16-Sep-2003	SHOP MEMO 6-25-03	

6. ISSUED BY	CODE	7. ADMINISTERED BY (If other than item 6)	CODE
NAVSEA INDIAN HEAD 101 STRAUSS AVE. ATTN: JESSICA MADDOX 1143I MADDOXJD@I H.NAVY.MIL INDIAN HEAD MD 20640-5035	N00174	**See Item 6**	

8. NAME AND ADDRESS OF CONTRACTOR (No., Street, County, State and Zip Code)		
	X	9A. AMENDMENT OF SOLICITATION NO. N00174-03-R-0050
	X	9B. DATED (SEE ITEM 11) 21-Aug-2003
		10A. MOD. OF CONTRACT/ORDER NO.
		10B. DATED (SEE ITEM 13)
CODE / FACILITY CODE		

11. THIS ITEM ONLY APPLIES TO AMENDMENTS OF SOLICITATIONS

[X] The above numbered solicitation is amended as set forth in Item 14. The hour and date specified for receipt of Offer [ ] is extended, [X] is not extended.

Offer must acknowledge receipt of this amendment prior to the hour and date specified in the solicitation or as amended by one of the following methods: (a) By completing Items 8 and 15, and returning 1 copies of the amendment; (b) By acknowledging receipt of this amendment on each copy of the offer submitted; or (c) By separate letter or telegram which includes a reference to the solicitation and amendment numbers. FAILURE OF YOUR ACKNOWLEDGMENT TO BE RECEIVED AT THE PLACE DESIGNATED FOR THE RECEIPT OF OFFERS PRIOR TO THE HOUR AND DATE SPECIFIED MAY RESULT IN REJECTION OF YOUR OFFER. If by virtue of this amendment you desire to change an offer already submitted, such change may be made by telegram or letter, provided each telegram or letter makes reference to the solicitation and this amendment, and is received prior to the opening hour and date specified.

12. ACCOUNTING AND APPROPRIATION DATA (If required)

13. THIS ITEM APPLIES ONLY TO MODIFICATIONS OF CONTRACTS/ORDERS. IT MODIFIES THE CONTRACT/ORDER NO. AS DESCRIBED IN ITEM 14.

[ ] A. THIS CHANGE ORDER IS ISSUED PURSUANT TO: (Specify authority) THE CHANGES SET FORTH IN ITEM 14 ARE MADE IN THE CONTRACT ORDER NO. IN ITEM 10A.

[ ] B. THE ABOVE NUMBERED CONTRACT/ORDER IS MODIFIED TO REFLECT THE ADMINISTRATIVE CHANGES (such as changes in paying office, appropriation date, etc.) SET FORTH IN ITEM 14, PURSUANT TO THE AUTHORITY OF FAR 43.103(B).

[ ] C. THIS SUPPLEMENTAL AGREEMENT IS ENTERED INTO PURSUANT TO AUTHORITY OF:

[ ] D. OTHER (Specify type of modification and authority)

E. IMPORTANT: Contractor [ ] is not, [ ] is required to sign this document and return _____ copies to the issuing office.

14. DESCRIPTION OF AMENDMENT/MODIFICATION (Organized by UCF section headings, including solicitation/contract subject matter where feasible.)

The purpose of this modification is to provide questions and answers concerning the subject solicitation and to incorporate clauses 52.215-1 (MAY 2001) and HQ L-2-0005 (JUNE 1994) into Section L.

Except as provided herein, all terms and conditions of the document referenced in Item 9A or 10A, as heretofore changed, remains unchanged and in full force and effect.

15A. NAME AND TITLE OF SIGNER (Type or print)		16A. NAME AND TITLE OF CONTRACTING OFFICER (Type or print)	
15B. CONTRACTOR/OFFEROR _____ (Signature of person authorized to sign)	15C. DATE SIGNED	16B. UNITED STATES OF AMERICA BY _____ (Signature of Contracting Officer)	16C. DATE SIGNED 16-Sep-2003

SECTION SF 30 BLOCK 14 CONTINUATION PAGE

1. The following questions and answers concerning the subject solicitation are being provided:

Question #1: Paragraph4.1.1 of the subject solicitation states that "the x-ray detection package for both systems will be capable of taking at least 16 bit data over its complete 14 by 17 inch area." The question we have is: does this mean that the detector must have 16 bit analog to digital converters or is it acceptable to use a detector with less than 16 bit A/D but store the data in 16 bit file format?

Answer #1: The Government is requesting something that can fill the full dynamic range of 16 bit data. Its digital or analog conversion is left up to the offeror.

Question #2: Will the Government accept proposals which provide solutions utilizing detectors which do not meet the requirements of the detector package as stated in paragraph 4.1.1, but which will meet the image quality requirements?

Answer #2: Proposals which provide solutions which do not meet the requirements of the detector package as stated in paragraph 4.1.1 will be accepted. However, these proposals will be evaluated in accordance with the evaluation criteria set forth in Sections L and M of the solicitation.

Question #3: Given the probability that the hurricane may it your area by Thursday of this week, will you accept our bid if we have proof that we sent it overnight on the 17th or 18th but FedX or UPS could not deliver due to the weather?

Answer #3: Offerors are directed to block 9 on page 1 of the solicitation. This block makes reference to FAR clause 52.215-1. Paragraph (c)(3)(iv) of this clause states, "If an emergency or unanticipated event interrupts normal Government processes so that proposals cannot be received at the office designated for receipt of proposals by the exact time specified in solicitation, and urgent Government requirements preclude amendment of the solicitation, the time specified for receipt of proposals will be deemed to be extended to the same time of day specified in the solicitation on the first work day on which normal Government processes resume." **At this time, NAVSEA Indian Head will be open during normal hours on Thursday, 18 September 2003 and Friday, 19 September 2003. Therefore, proposals are due by 3:00 PM EST on 19 September 2003.** However, if, due to inclement weather, proposals cannot be delivered to the building designated for receipt of proposals at the date and exact time specified in the solicitation, the Government will accept proposals after that date and time if offerors can provide proof (i.e., FedX or UPS tracking document) that indicates that the proposal was sent and scheduled to arrive by 3:00 PM EST on 19 September 2003. The Government will not accept proposals that are delivered later than 3:00 PM EST on 22 September 2003.

2. FAR clause 52.215-1 (MAY 2001) is hereby incorporated by reference into Section L of the subject solicitation.

3. Clause HQ L-2-0005 (JUNE 1994) is hereby incorporated in full into Section L of the subject solicitation. The text of the clause is as follows:

HQ L-2-0005 - NOTIFICATION OF POTENTIAL ORGANIZATIONAL CONFLICT(S) OF INTEREST (NAVSEA) (JUN 1994)

(a) Offerors are reminded that certain existing contractual arrangements may preclude, restrict or limit participation, in whole or in part, as either a subcontractor or as a prime contractor under this competitive

procurement. Of primary concern are those contractual arrangements in which the Offeror provides support to ____, or related laboratories (if applicable), in support of operation of the office or any of its programs. General guidance may be found in FAR 9.505; however, this guidance is not all inclusive. The Offeror's attention is directed to the "Organizational Conflict of Interest" (or similar) requirement which may be contained in current or completed contract(s) which prohibits the prime or subcontractor from providing certain supplies or services to the Government as described above during the period of the current "support" contract(s) or for a period after completion of the "support" contract(s). Notwithstanding the existence or non-existence of an Organizational Conflict of Interest (OCI) clause or similar requirement in current or completed contract(s), the offeror shall comply with FAR 9.5 and identify whether an OCI exists and not rely solely on the presence of an OCI requirement.

(b) If a potential conflict of interest exists at any tier, each potential prime offeror is requested to notify the Contracting Officer within 14 days of the date of this solicitation. The Offeror shall provide: (1) the contract number and name and phone number of the Contracting Officer for the contract which gives rise to a potential organizational conflict of interest; (2) a copy of the requirement; (3) the statement of work (or technical instruction) from the existing contract; (4) a brief description of the type of work to be performed by each subcontractor under the competitive procurement; and (5) any additional information the Contracting Officer should consider in making a determination of whether a conflict of interest exists. The Government may independently verify the information received from the offeror. Notwithstanding the above, the Government reserves the right to determine whether a conflict of interest exists based on any information received from any source.

(c) The Government will notify an offeror of any conflict of interest within 14 days of receipt of all required information. Those offerors deemed to have a conflict of interest may be ineligible for award. Failure to provide the information in a timely manner does not waive the Government's rights to make a conflict of interest determination. The offeror is notified that if it expends time and money on proposal preparation, such expenditure is at its own risk that the Government will not determine that an organizational conflict of interest exists.

(d) Any potential prime contractor which proposes a subcontractor later determined to have a conflict of interest and deemed ineligible to participate in the current competition, may not be granted the opportunity to revise its proposal to remove the ineligible subcontractor. The Government reserves the right to determine which offerors remain in the competitive range through the normal source selection process.

(e) If the offeror determines that a potential organizational conflict of interest does not exist at any tier, the offeror shall include a statement to that effect in its response to this solicitation.

4. All references to 29 CFR 1020.40 in Sections L and M of the subject solicitation are hereby changed to 21 CFR 1020.40. The text of this section of the Code Of Federal Regulations can be found at the end of this document.

5. All other terms and conditions remain unchanged.

6. For further information, contact Jessica Maddox at maddoxjd@ih.navy.mil.

TITLE 21--FOOD AND DRUGS

CHAPTER I--FOOD AND DRUG ADMINISTRATION, DEPARTMENT OF HEALTH AND HUMAN SERVICES (CONTINUED)

PART 1020--PERFORMANCE STANDARDS FOR IONIZING RADIATION EMITTING PRODUCTS--Table of Contents

(a) Applicability. The provisions of this section are applicable to cabinet x-ray systems manufactured or assembled on or after April 10, 1975, except that the provisions as applied to x-ray systems designed primarily for the inspection of carry-on baggage are applicable to such systems manufactured or assembled on or after April 25, 1974. The provisions of this section are not applicable to systems which are designed exclusively for microscopic examination of material, e.g., x- ray diffraction, spectroscopic, and electron microscope equipment or to systems for intentional exposure of humans to x-rays.

(b) Definitions. As used in this section the following definitions apply:

(1) Access panel means any barrier or panel which is designed to be removed or opened for maintenance or service purposes, requires tools to open, and permits access to the interior of the cabinet.

(2) Aperture means any opening in the outside surface of the cabinet, other than a port, which remains open during generation of x radiation.

(3) Cabinet x-ray system means an x-ray system with the x-ray tube installed in an enclosure (hereinafter termed cabinet) which, independently of existing architectural structures except the floor on which it may be placed, is intended to contain at least that portion of a material being irradiated, provide radiation attenuation, and exclude personnel from its interior during generation of x radiation. Included are all x-ray systems designed primarily for the inspection of carry-on baggage at airline, railroad, and bus terminals, and in similar facilities. An x-ray tube used within a shielded part of a building, or x-ray equipment which may temporarily or occasionally incorporate portable shielding is not considered a cabinet x-ray system.

(4) Door means any barrier which is designed to be movable or opened for routine operation purposes, does not generally require tools to open, and permits access to the interior of the cabinet. For the purposes of paragraph (c)(4)(i) of this section, inflexible hardware rigidly affixed to the door shall be considered part of the door.

(5) Exposure means the quotient of dQ by dm where dQ is the absolute value of the total charge of the ions of one sign produced in air when all the electrons (negatrons and positrons) liberated by photons in a volume element of air having mass dm are completely stopped in air. [[Page 626]]

(6) External surface means the outside surface of the cabinet x-ray system, including the high-voltage generator, doors, access panels, latches, control knobs, and other permanently mounted hardware and including the plane across any aperture or port.

(7) Floor means the underside external surface of the cabinet.

(8) Ground fault means an accidental electrical grounding of an electrical conductor.

(9) Port means any opening in the outside surface of the cabinet which is designed to remain open, during generation of x-rays, for the purpose of conveying material to be irradiated into and out of the cabinet, or for partial insertion for irradiation of an object whose dimensions do not permit complete insertion into the cabinet.

(10) Primary beam means the x radiation emitted directly from the from the target and passing through the window of the x-ray tube.

(11) Safety interlock means a device which is intended to prevent the generation of x radiation when access by any part of the human body to the interior of the cabinet x-ray system through a door or access panel is possible.

(12) X-ray system means an assemblage of components for the controlled generation of x-rays.

(13) X-ray tube means any electron tube which is designed for the conversion of electrical energy into x-ray energy.

(c) Requirements--(1) Emission limit. (i) Radiation emitted from the cabinet x-ray system shall not exceed an exposure of 0.5 milliroentgen in one hour at any point five centimeters outside the external surface.

(ii) Compliance with the exposure limit in paragraph (c)(1)(i) of this section shall be determined by measurements averaged over a cross- sectional area of ten square centimeters with no linear dimension greater than 5 centimeters, with the cabinet x-ray system operated at those combinations of x-ray tube potential, current, beam orientation, and conditions of scatter radiation which produce the maximum x-ray exposure at the external surface, and with the door(s) and access panel(s) fully closed as well as fixed at any other position(s) which will allow the generation of x radiation.

(2) Floors. A cabinet x-ray system shall have a permanent floor. Any support surface to which a cabinet x-ray system is permanently affixed may be deemed the floor of the system.

(3) Ports and apertures. (i) The insertion of any part of the human body through any port into the primary beam shall not be possible.

(ii) The insertion of any part of the human body through any aperture shall not be possible.

(4) Safety interlocks. (i) Each door of a cabinet x-ray system shall have a minimum of two safety interlocks. One, but not both of the required interlocks shall be such that door opening results in physical disconnection of the energy supply circuit to the high-voltage generator, and such disconnection shall not be dependent upon any moving part other than the door.

(ii) Each access panel shall have at least one safety interlock.

(iii) Following interruption of x-ray generation by the functioning of any safety interlock, use of a control provided in accordance with paragraph (c)(6)(ii) of this section shall be necessary for resumption of x-ray generation.

(iv) Failure of any single component of the cabinet x-ray system shall not cause failure of more than one required safety interlock.

(5) Ground fault. A ground fault shall not result in the generation of x-rays.

(6) Controls and indicators for all cabinet x-ray systems. For all systems to which this section is applicable there shall be provided:

(i) A key-actuated control to insure that x-ray generation is not possible with the key removed.

(ii) A control or controls to initiate and terminate the generation of x-rays other than by functioning of a safety interlock or the main power control.

(iii) Two independent means which indicate when and only when x-rays are being generated, unless the x-ray generation period is less than one-half second, in which case the indicators shall be activated for one-half second, and which are discernible from any point at which initiation of x-ray generation is possible. Failure of a single component [[Page 627]] of the cabinet x-ray system shall not cause failure of both indicators to perform their intended function. One, but not both, of the indicators required by this subdivision may be a milliammeter labeled to indicate x-ray tube current. All other indicators shall be legibly labeled ``X- RAY ON''.

(iv) Additional means other than milliammeters which indicate when and only when x-rays are being generated, unless the x-ray generation period is less than one-half second in which case the indicators shall be activated for one-half second, as needed to insure that at least one indicator is visible from each door, access panel, and port, and is legibly labeled ``X-RAY ON''.

(7) Additional controls and indicators for cabinet x-ray systems designed to admit humans. For cabinet x-ray systems designed to admit humans there shall also be provided:

(i) A control within the cabinet for preventing and terminating x- ray generation, which cannot be reset, overridden or bypassed from the outside of the cabinet.

(ii) No means by which x-ray generation can be initiated from within the cabinet.

(iii) Audible and visible warning signals within the cabinet which are actuated for at least 10 seconds immediately prior to the first initiation of x-ray generation after closing any door designed to admit humans. Failure of any single component of the cabinet x-ray system shall not cause failure of both the audible and visible warning signals.

(iv) A visible warning signal within the cabinet which remains actuated when and only when x-rays are being generated, unless the x-ray generation period is less than one-half second in which case the indicators shall be activated for one-half second.

(v) Signs indicating the meaning of the warning signals provided pursuant to paragraphs (c)(7) (iii) and (iv) of this section and containing instructions for the use of the control provided pursuant to paragraph (c)(7)(i) of this section. These signs shall be legible, accessible to view, and illuminated when the main power control is in the ``on'' position.

(8) Warning labels. (i) There shall be permanently affixed or inscribed on the cabinet x-ray system at the location of any controls which can be used to initiate x-ray generation, a clearly legible and visible label bearing the statement: Caution: X-Rays Produced When Energized

(ii) There shall be permanently affixed or inscribed on the cabinet x-ray system adjacent to each port a clearly legible and visible label bearing the statement: caution: Do Not Insert Any Part of the Body When System is Energized--X- ray Hazard

(9) Instructions. (i) Manufacturers of cabinet x-ray systems shall provide for purchasers, and to others upon request at a cost not to exceed the cost of preparation and distribution, manuals and instructions which shall include at least the following technical and safety information: Potential, current, and duty cycle ratings of the x- ray generation equipment; adequate instructions concerning any radiological safety procedures and precautions which may be necessary because of unique features of the system; and a schedule of maintenance necessary to keep the system in compliance with this section.

(ii) Manufacturers of cabinet x-ray systems which are intended to be assembled or installed by the purchaser shall provide instructions for assembly, installation, adjustment and testing of the cabinet x-ray system adequate to assure that the system is in compliance with applicable provisions of this section when assembled, installed, adjusted and tested as directed.

(10) Additional requirements for x-ray baggage inspection systems. X-ray systems designed primarily for the inspection of carry-on baggage at airline, railroad, and bus terminals, and at similar facilities, shall be provided with means, pursuant to paragraphs (c)(10) (i) and (ii) of this section, to insure operator presence at the control area in a position which permits surveillance of the ports and doors during generation of x-radiation.

(i) During an exposure or preset succession of exposures of one-half second [[Page 628]] or greater duration, the means provided shall enable the operator to terminate the exposure or preset succession of exposures at any time.

(ii) During an exposure or preset succession of exposures of less than one-half second duration, the means provided may allow completion of the exposure in progress but shall enable the operator to prevent additional exposures.

(d) Modification of a certified system. The modification of a cabinet x-ray system, previously certified pursuant to Sec. 1010.2 by any person engaged in the business of manufacturing, assembling or modifying cabinet x-ray systems shall be construed as manufacturing under the act if the modification affects any aspect of the system's performance for which this section has an applicable requirement. The manufacturer who performs such modification shall recertify and reidentify the system in accordance with the provisions of Secs. 1010.2 and 1010.3 of this chapter.